Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BARBARA PAYNE, *Plaintiff,* v. BIOMET, INC., et al., *Defendants.*	Civil Action No. 18-13396 **OPINION**

John Michael Vazquez, U.S.D.J.

This case concerns an allegedly defective hip replacement. D.E. 1-1. Plaintiff Barbara Payne alleges that Defendants[1] "designed, developed, manufactured, tested, labeled, marketed, promoted, distributed, and sold" a defective Biomet M2a-Magnum metal-on-metal prosthetic hip replacement device (the "Magnum"), which Plaintiff had implanted in her right hip in 2006. *Id.* Currently pending before the Court is Defendants' motion to dismiss Counts V, VI, VII, VIII, IX, X, and XI[2] of the Plaintiff's First Amended Complaint ("FAC") pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim. D.E. 3. The Court reviewed the parties' submissions in support

[1] Defendants include Biomet, Inc.; Biomet Orthopedics, Inc.; Biomet Orthopedics, LLC; Biomet Manufacturing Corp.; Biomet Manufacturing, LLC; Biomet Fair Lawn, LP; Biomet Fair Lawn, LLC; Biomet US Reconstruction, LLC; Zimmer Biomet Holdings, Inc.; ABC Company(s) 1-50; and their agents, servants, and employees (collectively "Defendants" or "Biomet"). D.E. 1-1.

[2] In captioning their motion initially, Defendants mistakenly included Count XII instead of Count VI. *See* D.E. 3; Def. Br; Def. Reply at 1, n. 1. In their moving brief, however, Defendants argued for the dismissal of Count VI, not Count XII. Def. Br. at 11. Plaintiff recognized this captioning error and correctly addressed Count VI rather than Count XII in its opposition. Pl. Opp'n at 11-13. Thus, the Court analyzes the parties' arguments as to Count VI, not Count XII.

and in opposition[3] and decided the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons stated below, Defendant's motion to dismiss is granted.

I. INTRODUCTION[4]

On September 19, 2006, Plaintiff, a New Jersey resident, underwent hip replacement surgery at Cara Maass Hospital in Belleville, New Jersey, whereby orthopedic surgeon Dr. Frank Femino implanted a Magnum in Plaintiff's right hip. *Id.* ¶¶ 1, 2, 4, 27. Defendants, mainly Indiana companies, "designed, manufactured, marketed, promoted and sold the Magnum." *Id.* ¶¶ 7, 18, 20. Plaintiff alleges that the Magnum was defective and caused Plaintiff harm by, at a minimum, exposing Plaintiff to metal poisoning and requiring that Plaintiff undergo two more surgeries. *Id.* ¶ 5.

On August 1, 2018, Plaintiff filed her FAC against Defendants in the Superior Court of New Jersey, Hudson County, alleging thirteen counts: (I) manufacturing defect; (II) design defect; (III) defect due to non-conformance with representations; (IV) failure to warn; (V) negligence; (VI) breach of express warranty; (VII) breach of implied warranty; (VIII) negligent misrepresentation; (IX) fraudulent misrepresentation; (X) fraudulent concealment; (XI) violation of the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. § 56:8-1 *et seq.*; (XII) violation of the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. § 2A:58C-1 *et seq.*; and (XIII)

---

[3] Defendants' brief in support of their motion will be referred to as "Def. Br.," D.E. 3-1; Plaintiff's opposition will be referred to as "Pl. Opp'n," D.E. 11; Defendants' reply will be referred to as "Def. Reply," D.E. 12.

[4] The facts are derived from Plaintiff's FAC. D.E. 1-1 ("FAC"). When reviewing a motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Additionally, a district court may consider "exhibits attached to the complaint and matters of public record" as well as "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

punitive damages.[5] FAC ¶¶ 63-176. On August 30, 2018, Defendants removed this action pursuant to 28 U.S.C. § 1441(a) on the basis of diversity jurisdiction under 28 U.S.C. § 1332(a)(1). D.E. 1. Defendants then moved to dismiss Counts V (negligence), VI (breach of express warranty), VII (breach of implied warranty), VIII (negligent misrepresentation), IX (fraudulent misrepresentation), X (fraudulent concealment), and XI (NJCFA) of Plaintiff's FAC pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim. Plaintiff opposed this motion, D.E. 11, and Defendants replied, D.E. 12.

II. LEGAL STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a count for "failure to state a claim upon which relief can be granted[.]" To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (internal quotation marks and citations omitted). As a result, a plaintiff must "allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of [his] claims." *Id.* at 789.

In evaluating the sufficiency of a complaint, a district court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff.

[5] Plaintiff brought punitive damages as a separate count rather than alleging the damages as a form of relief.

Phillips v. Cty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008). A court, however, is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007). If, after viewing the allegations in the complaint most favorable to the plaintiff, it appears that no relief could be granted under any set of facts consistent with the allegations, a court may dismiss the complaint for failure to state a claim. *DeFazio v. Leading Edge Recovery Sols.*, 2010 WL 5146765, at *1 (D.N.J. Dec. 13, 2010).

"Independent of the standard applicable to Rule 12(b)(6) motions, Rule 9(b) imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). Pursuant to Rule 9(b), when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake . . . [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A party alleging fraud must therefore support its allegations with factual details such as "the who, what, when, where and how of the events at issue." *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016). Accordingly, "[t]o satisfy the particularity standard, 'the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.'" *Feingold v. Graff*, 516 F. App'x 223, 226 (3d Cir. 2013) (citing *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)). This heightened pleading standard is designed to "ensure that defendants are placed on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of fraud." *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (internal quotation marks omitted).

III. ANALYSIS

Defendants make two arguments: (1) that Counts V, VII, VIII, IX, X, and XI of the Plaintiff's FAC are subsumed by the NJPLA and therefore must be dismissed, Def. Br. at 1, 4-11; and (2) that Plaintiff fails to plausibly plead Count VI for breach of an express warranty, *id.* at 11.

The NJPLA provides that

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose[.]

N.J.S.A. § 2A:58C-2. The NJPLA defines "product liability action" as "any claim or action brought by a claimant for harm caused by a product, *irrespective of the theory underlying the claim*, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3) (emphasis added). The statute also defines "harm" as

> (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or *other loss deriving from* any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. § 2A:58C-1(b)(2) (emphasis added).

"When read in light of these definitions, it becomes clear that [the NJPLA] effectively creates an exclusive statutory cause of action for claims falling within its purview." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991); *see also In re Lead Paint Litig.*, 191 N.J. 405, 436-37 (2007) ("The language chosen by the Legislature in enacting the [NJ]PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products."). Thus, "the [NJ]PLA is the exclusive remedy for harms caused by a product." *DeBenedetto v. Denny's, Inc.*, 421 N.J. Super. 312, 319 (Law. Div. 2010), *aff'd*, No. 09-4135, 2011 WL 67258 (App. Div. Jan. 11, 2011); *see also Sinclair v. Merck & Co.*,

195 N.J. 51, 66 (2008) ("[T]he [NJ]PLA is paramount when the underlying claim is one for harm caused by a product.").

Plaintiff concedes that "partial dismissal of the [disputed] claims is appropriate to the extent they seek damages for personal physical injuries caused by the Defendants' allegedly defective Magnum [product]." Pl. Opp'n at 10. While the Court agrees that the NJPLA subsumes claims for personal physical injuries caused by a product, the Court disagrees that this is the only type of harm covered by the statute. Again, the "harm" covered by the NJPLA expressly extends to personal physical injuries, "pain and suffering," "physical damage to property," "*or other harm deriving from*" these harms. N.J.S.A. § 2A:58C-1(b)(2) (emphasis added).

Here, Plaintiff's alleged harms are either personal physical injuries from the Magnum, *or additional harms deriving therefrom*. Compl. ¶¶ 61-62. Specifically, in her FAC, Plaintiff alleges in her damages section (applicable to all counts) that

> *[a]s a direct result of her defective Magnum Device*, toxic metal debris was released into Plaintiff's body and accumulated in the tissues and bone surrounding her Magnum Device. *This resulted in* Plaintiff suffering severe pain, inflammation, lack of mobility, severe debilitation, tissue death, bone damage, pathological fracture to her sacrum and pelvis that were not trauma related, metal poisoning and metallosis. *As a consequence of the metallosis*, Plaintiff's right hip implant failed earlier than it should have. Furthermore, the damage caused to her tissue and bone made revision surgery more complex, onerous, and risky. *As a consequence of her metallosis*, Plaintiff required revision surgery to remove and replace the Magnum Device. As a matter of complication, *relating to metallosis* and not, Plaintiff required a second revision surgery months later which included the implantation of a metal plate and screws into her hip. Plaintiff developed bilateral deep vein thrombosis following that surgery.

Id. ¶ 61 (emphases added). Plaintiff continues that "*[a]s a result of her defective Magnum Device*, Plaintiff also suffered mental pain and anguish, emotional distress and loss of earnings." *Id.* ¶ 62

(emphasis added). Plaintiff does not allege any other damages.[6] Thus, whether as a personal physical injury, or harm deriving therefrom, all of Plaintiff's claims are for "harm caused by a product" within the purview of the NJPLA.[7] *See Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 45 (D.N.J. 1993) ("Plaintiffs cannot avoid the physical harm requirement by recasting their product liability claims as [other] claims."). The Court dismisses Counts V (negligence), VII (breach of implied warranty), VIII (negligent misrepresentation), IX (fraudulent misrepresentation), X (fraudulent concealment), and XI (NJCFA) with prejudice as they are subsumed by the NJPLA. *See, e.g., Bailey v. Wyeth, Inc.*, 424 N.J. Super. 278, 335 (Law. Div. 2008) (similarly dismissing a plaintiff's non-NJPLA claims for harm caused by a product).

Defendants next argue that Plaintiff fails to plausibly state a claim for breach of an express warranty. Def. Br. at 11. A claim for breach of an express warranty is not subsumed by the NJPLA. N.J.S.A. § 2A:58C-1(b)(3) (stating that the NJPLA covers "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, *except actions for harm caused by breach of an express warranty*.") (emphasis added). In New Jersey, a plaintiff must allege the following to state a claim for breach of express warranty: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Snyder v. Farnam*

---

[6] For example, Plaintiff does not allege in her FAC that she is seeking to recover for damage to the Magnum itself, which is expressly not covered by the NJPLA. *See* N.J.S.A. § 2A:58C-1(b)(2) (defining a covered harm to include "physical damage to property, *other than to the product itself*") (emphasis added).

[7] In addition to the overarching damages section, each count individually alleges (either directly or indirectly) that the Magnum caused the injury alleged in that count. *See* Compl. ¶¶ 99 (negligence), 114-15 (implied warranty), 121 (negligent misrepresentation); 130 (fraudulent misrepresentation); 146 (fraudulent concealment); 158 (NJCFA).

Companies, Inc., 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (citing N.J.S.A. § 12A:2-313); *see also Topoleski v. Veshi*, No. 16-1820, 2019 WL 149721, at *6 (N.J. Super. Ct. App. Div. Jan. 8, 2019). As to the "basis of the bargain" element, the plaintiff must allege that she "read, heard, saw or knew of the advertisement containing the [express warranty]" when choosing to use the product. *Metcalfe v. Biomet, Inc.*, No. 18- 456, 2019 WL 192902, at *3 (D.N.J. Jan. 15, 2019) (citing *Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 567 (3d Cir. 1990), *overruled on other grounds*, 505 U.S. 504 (1992)).

Here, Plaintiff alleges that "Plaintiff decided to use the metal-on-metal option based on *Dr. Femino's* representations and recommendation" that the Magnum was "the better option because it was a newer technology and had a longer life span." FAC ¶ 27 (emphasis added). Dr. Femino is not a Defendant in this action. Plaintiff instead brings this express warranty claim against *Defendants*, who Plaintiff "[u]pon information and belief" alleges, "utilized employees, servants and/or agents to aggressively promote, distribute, and sell the Magnum Device to surgeons and health care providers in the State of New Jersey, including Plaintiff's implanting physician, Dr. Frank Femino." *Id.* ¶ 44. Plaintiff also alleges "[u]pon information and belief" that "Defendants and/or their employees, agents, or representatives met with orthopedic surgeons, including Dr. Femino, to promote the Magnum Device" and that

> [d]uring these meetings, [Defendants] and [their] representatives assured the orthopedic surgeons, including Dr. Femino, that the Magnum Device was safe and effective, was the best and most advanced product on the market, had an excellent track record, would last longer than traditional and alternative hip implant products, had low and acceptable failure rates, and was safer and more effective than other hip implant products.

Id. ¶ 46. Plaintiff, however, does not identify who, specifically, from Defendants made these representations to Dr. Femino. Plaintiff does not identify when the alleged "meeting" with Dr.

Femino took place, where it took place, and who from Defendants was present. Thus, Plaintiff has not plausibly alleged any express warranty made by Defendants to Dr. Femino, which Dr. Femino relied upon to advise Plaintiff, and Plaintiff then relied upon to form the basis of her decision to implant the Magnum.[8]

Plaintiff cites to a 2004 publication entitled "Metal Ions-Scientific Review," in which Defendants stated that "extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants" and that "cobalt and chromium may be beneficial to the body as established by research and listed by the US Government" – which Plaintiff claims to be misrepresentations. *Id.* ¶ 41. Additionally, Plaintiff references a Biomet advertising campaign involving Olympic gymnast Mary Lou Retton where Defendants allegedly continued using Retton's name for promotional purposes even after Retton's Magnum implant failed and needed to be removed. *Id.* ¶ 42. Plaintiff alleges "[u]pon information and belief" that "the[se] representations and/or omissions were made to Dr. Femino either directly . . . or indirectly through promotional, marketing and educational materials." *Id.* ¶ 48.

Plaintiff's allegations lack the requisite specificity to make them plausible rather than simply possible. Plaintiff is essentially speculating as to the information Defendants provided to Dr. Femino. Plaintiff does not allege that Dr. Femino was aware of, or relied on, the 2004 publication or on the Retton advertising campaign. Plaintiff similarly does not allege that she ever reviewed, much less relied on, the cited materials. *See, e.g., Metcalfe*, 2019 WL 192902, at *7 ("[I]f a plaintiff does not plead that he saw the alleged warranty, then a court cannot *reasonably*

[8] Both parties appear to assume that an express warranty claim can be maintained if the warranty was made to the physician in the first instance. As a result, the Court assumes that this is a viable legal theory in deciding the current motion.

infer that the warranty formed a basis of the bargain."). The Court dismisses Plaintiff's breach of express warranty claim (Count VI) without prejudice.

IV. CONCLUSION

In sum, the Court grants Defendant's motion to dismiss Counts V, VI, VII, VIII, IX, X, and XI of Plaintiff's FAC pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim (D.E. 3). Counts V, VII, VIII, IX, X, and XI are dismissed with prejudice, as they are subsumed by the NJPLA. Count VI is dismissed without prejudice. Plaintiff has thirty (30) days to file a Second Amended Complaint, if she so chooses, consistent with this Opinion. If Plaintiff fails to file a Second Amended Complaint, the dismissal of Count VI will be with prejudice. An appropriate Order accompanies this Opinion.

Dated: July 2, 2019

John Michael Vazquez, U.S.D.J.